## Remarks

This Amendment and Response amends claim 12. With this Amendment and Response, claim 12 is currently under examination and claims 1-11 have been withdrawn in response to a restriction requirement.

## I. Amendments to the Specification

The Action objected to the specification because it contained an embedded hyperlink and/or other form of browser-executable code. Applicants have amended the disclosure to correct this error. No new matter has been added. Applicants thus submit that the Action's objection has been overcome and request that the objection be withdrawn.

Applicants have updated the claim of priority section of the specification to reflect the current status of the recited applications.

## II. 35 U.S.C §112 Rejections

Claim 12 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Action states that the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully disagree.

Applicants invention relates, at least in part, to the oral delivery of their proprietary particles to a patient in need thereof, wherein the proprietary particles comprise a layer comprising casein at least partially coating the particle. The proprietary particles comprise, at least in part, calcium phosphate particles and therapeutic agents. As specified in Applicants' disclosure, the therapeutic agents "may be any therapeutically effective agent, such as a protein, a peptide, a hormone, such as insulin, or even more particularly, recombinant or native human

insulin, a steroid, an enzyme, a small drug molecule, a therapeutic antibody, a vaccine," or any combination of the above. The invention lies, at least in part, in the oral delivery of the Applicants' proprietary particles comprising calcium phosphate and any of these therapeutic agents. Neither the particles, nor their oral delivery, are dependent upon the structure or the function of the therapeutic agents. Applicants' disclosure allows one of ordinary skill in the art to recognize that Applicants had possession of their invention as claimed; it is not necessary for Applicants to describe every single genus to which the claims are drawn.

Respectfully, the Examiner has not met his burden of presenting evidence why one skilled in the art would not recognize that the written description of the invention provides support for Claim 12. Moreover, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *See* MPEP 2163, *In re Wertheim*, 541 F.2d 257,263 (CCPA 1965).

Claim 12 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 was rejected as vague and indefinite by reciting the phrase "therapeutic amount." "Therapeutic amount," as well known to those skilled in the art, is the amount required to have the desired therapeutic effect. Applicants respectfully submit that it is not necessary that they state the therapeutic amount for each therapeutic function which could be achieved.

**III. 35 U.S.C. §103 Rejection**

Claim 12 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lee et al in view of Corrigan et al. The Action states that Lee differs from the instant invention in that they don't disclose the use of casein as a coating substance for the calcium phosphate particles. The

Action further states that Corrigan discloses the use of casein in pharmaceutical compositions to reduce the irritating effects of the active ingredient and to provide controlled release pharmaceutical compositions for oral administration.

Applicants respectfully submit that the particles of the present invention are quite different from those disclosed in Lee or Corrigan. The particles of the present invention are produced by reconstructing casein micelles around therapeutic agent-loaded CAP particles for the purpose of creating a protective coat surrounding the CAP-therapeutic agent particles. The particles will be in a collapsed conformation in acidic media, such as the gastric fluid of the stomach, due to agglomeration of micelles. The release of therapeutic agent from the formulation will be in less acidic media, such as in the small intestine, where the collapsed conformation will start to relax, allowing the drug to diffuse into the surrounding tissue and eventually the blood stream.

In contrast, the particles of Corrigan are formed generally by "mixing and compression, granulation processes,... spray drying or freeze drying the components together." The casein portion of the particle composition of Corrigan provides for the controlled release of a pharmaceutical formulation. Neither Corrigan nor Lee disclose a particle with a casein layer at least partially covering a core comprising calcium phosphate. As the references, alone or in combination, do not teach of suggest each limitation of Claim 12, Claim 12 is neither anticipated nor made obvious. Applicants thus respectfully request reconsideration of the rejection.

## PETITION FOR EXTENSION OF TIME

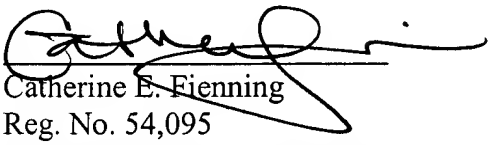
Applicants petition the Commissioner for Patents for a three-month extension of time, through and including October 5, 2004, to respond to the Office Action mailed April 5, 2004. Enclosed is a check in the amount of $490 in payment of the requisite fee for a three month time extension for a small entity.

The Commissioner is authorized to charge any additional fee relating to this filing to Deposit Account No. 11-0855.

## CONCLUSION

Applicants respectfully submit that claim 12 is in condition for immediate allowance, and request early notification to that effect.

Respectfully submitted,



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